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EXAMINER

SAUCIER, S

ART UNIT

PAPER NUMBER

1651

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DATE MAILED:

08/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/923,783

Applicant(s)
Roser et al.

Examiner
Sandra Saucier

Group Art Unit
1651



☒ Responsive to communication(s) filed on May 9, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-10, 12, 13, 15-23, 26-42, 44-48, 54-59, 61-67, 69, 71, 72, and 78-98 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 91-96 is/are allowed.

☒ Claim(s) 1-9, 13, 15-23, 26-36, 44, 45, 54-59, 61-67, 69, 71, 72, 78-81, 83, 84, 86-90, 97, 98 is/are rejected.

☒ Claim(s) 10, 12, 37-42, 46-48, 82, and 85 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 28

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Claims 1-10, 12, 13, 15-23, 26-42, 44-48, 54-59, 61-67, 69, 71, 72, 78-98 are pending and under examination.

Thank you for the new list of claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-6, 8, 9, 13, 15-23, 26-36, 44-45, 54-59, 61-67, 69, 71, 72, 78, 79, 81, 83, 84, 86-90, 97, 98 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Annear [3].

Annear [3] discloses a method of adding an aqueous bacterial suspension to a dried mixture of peptone, dextran/dextrin and glucose to form a viscous suspension of bacteria, placing the liquid suspension under vacuum (10mm Hg) which necessarily removes water from the suspension, then foaming under 0.1-0.05 mm Hg thereby forming a stable dried foam comprising bacteria, peptone, dextran/dextrin and glucose. The foams are stored and then rehydrated and the suspensions assayed for viability of the bacteria.

With regard to the limitation "chemically or enzymatically modified carbohydrate". All carbohydrates may be said to be enzymatically modified. During gluconeogenesis, glucose-6-phosphate is converted to glucose and other carbohydrates. Therefore, glucose can be said to be enzymatically modified.

With regard to the limitation of "an aqueous buffer" in claim 9, please note that the broth used to suspend the bacteria contains amino acids which provide buffering capacity.

With regard to the residual moisture limitation, although the reference does not measure residual moisture, it is considered to be within the range as claimed because the method as disclosed by Annear has the same method steps as the claimed method. Therefore, the product of the same method steps should be the same product in the absence of evidence to the contrary.

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With regard to an additive being a viscosity modifier or foam stabilizing agent, please note that dextran or dextrin as well as glucose is mixed with the bacterial suspension. These may be termed viscosity modifiers as well as foam stabilizing agents.

With regard to claims 55, 56, 57, 87, 88, the substance being preserved by Annear are bacteria. Bacteria contain proteins, lipids, enzymes and other substances which may also be termed, "physiologically active molecules" (claim 87) etc. and may be used as vaccines, especially disease associated bacteria as Annear's are, see Table 2. Bacteria may also have pharmaceutical activity or be part of a diagnostic reagent (for example, used for antigen-antibody determinations). Closure of the claim language might eliminate this reference from at least some of them.

Although Annear does not measure the viscosity of his suspension, it is considered to be within the viscosity limits of claim 79 because the concentration of carbohydrates in the starting material (suspension) of Annear is about 10% which falls within the concentration of the instant starting materials. Thus, the properties of such as suspension, such as viscosity, may reasonably be expected to also fall within the claimed limits in the absence of evidence to the contrary. Please check this viscosity limitation as it seems very high. Also, viscosity depends on temperature which is not stipulated.

With regard to claim 81, a bacteria might be interpreted to be a "chemotherapeutic" or an "antimicrobial" if used as a vaccine. Please note that the bacteria of the reference appear to be associated with disease. The lack of specific definition of these terms in the specification leaves their interpretation broadly open.

Claim Rejections - 35 USC § 103

Claims 7, 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Annear in combination with US 5,955,448 [A] or US 5,364,756 [B].

The claims are directed to the use of trehalose as a constituent of the foamed matrix.

The primary reference has been discussed above and lacks the use of trehalose as a constituent of the foamed matrix.

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US 5955448 teaches that trehalose is uniquely potent in prolonging the shelf life of dried proteins and other biological materials... (col. 2, l. 1-18).

US 5364756 discloses that trehalose is a dry protectant (col. 9, l. 30).

The addition or substitution of trehalose with/for the glucose in the method of Annear would have been obvious when the disclosures of US 5364756 or US 5955448 were taken with the primary reference because both '756 or '448 teach that trehalose is a protectant of biological materials during drying.

One of skill in the art may substitute or add trehalose to a composition used in a known drying process for the benefits, such as protection or stabilization of biomaterials in the dry state, which are also known.

Claims 10, 12, 37-42, 46-48, 82 and 85 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 5/9/00 prompted the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(I). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

To aid in correlating any papers for this application, all further

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correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Service Desk at (703) 308-0196. The number of the Fax Center for the faxing of papers is (703) 308-4227.

A handwritten signature in black ink, appearing to be 'Sandra Saucier', with a long horizontal stroke extending to the right.

Sandra Saucier
Primary Examiner
Art Unit 1651
August 3, 2000